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Original research article

Postplacental insertion of the levonorgestrel intrauterine device after cesarean delivery vs. delayed insertion: a randomized controlled trial☆,☆☆,★

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Abstract

Objective: This trial was designed to compare levonorgestrel intrauterine device (LNG-IUD) use at 1 year after delivery between women randomized to postplacental insertion at the time of cesarean delivery and delayed insertion 4–8 weeks after delivery.
Study design: This randomized controlled trial was conducted at two urban medical centers. Eligible pregnant women with planned cesarean deliveries were randomized to immediate postplacental insertion during cesarean or delayed insertion after 4–8 weeks. We used intention-to-treat analysis for the primary outcome of LNG-IUD use 12 months after delivery.
Results: Forty-two women were randomized, 20 into the postplacental group and 22 in the delayed group. Although confirmed use of the LNG-IUD 12 months after delivery was higher in the postplacental group (60.0% vs. 40.9%, p=.35), this difference was not statistically significance. Expulsion was significantly more common in the postplacental group (20.0% vs. 0%, p=.04). There were significant differences between the two sites in baseline population characteristics, follow-up and expulsion. The trial did not answer the intended question as it was halted early due to slow enrollment.
Conclusions: Our results show higher expulsion after postplacental insertion compared to delayed insertion but suggest similar IUD use at 12 months. Moreover, it provides valuable lessons regarding a randomized controlled trial of postplacental LNG-IUD placement due to the challenges of estimating effect size and the nature of the population who might benefit from immediate insertion.
Implications: Postplacental insertion of an IUD may improve use of highly effective contraception during the postpartum period. While our results suggest higher expulsion after postplacental insertion compared to delayed insertion and similar IUD use at 12 months, our trial was insufficient to definitively test our hypothesis.

Keywords: Intrauterine device; Contraception; Postplacental; Postpartum; Cesarean

1. Introduction

Many postpartum women do not receive contraception until their postpartum visit, which often does not occur until 6 weeks. This delay may put some women at risk for unintended pregnancy, as many resume sexual activity prior to that visit [1]. The intrauterine device (IUD) may be an ideal method for immediate postpartum administration as it facilitates adequate birth spacing and does not require repeat visits for contraceptive refills. However, the IUD remains underused in the United States, with only 3.5% of US women reporting current use [2]. Barriers to uptake include cost, lack of provider knowledge or availability, two-visit protocols for insertion and misconceptions about IUDs [3–6]. While little is known about postpartum IUD uptake, one study of adolescents who expressed a desire for an IUD showed multiple barriers to uptake, including outdated eligibility restrictions, long wait times and lack of insurance coverage [7].

Placing an IUD immediately after delivery may help overcome some barriers to uptake. Immediate postplacental

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insertion of an IUD (within 10 min of delivery of the placenta) has been studied in a number of populations and is practiced worldwide [8]. Nevertheless, few randomized controlled trials (RCTs) compare postplacental insertion to delayed insertion, and we found no published RCTs investigating postplacental insertion at the time of cesarean delivery [8]. While postplacental insertion is safe and effective, expulsion rates are higher compared to those of interval insertion, with expulsion after vaginal delivery higher than that after cesarean delivery [9]. Although expulsion for postplacental insertion after cesarean delivery appears to be higher than that after interval insertion, in some studies, as few as 45%–60% of women return for delayed postpartum IUD placement [9–13].

In this trial, we designed a novel RCT to compare levonorgestrel intrauterine device (LNG-IUD) use at 1 year after delivery between women randomized to postplacental insertion at the time of scheduled cesarean delivery and those with delayed insertion 4–8 weeks after cesarean delivery.

2. Materials and methods

This randomized, controlled, parallel-group trial was conducted at The University of Chicago Medical Center (UCMC) from May 2007 to July 2010. The NorthShore University HealthSystem Evanston Hospital (EH) site was added due to slow recruitment at UCMC, and the trial was conducted there from April 2009 to January 2011. The trial received Institutional Review Board approval at both sites. Pregnant English-speaking women, aged 18 years and older, with planned cesarean delivery and desiring the LNG-IUD were eligible. Women with an allergy to the device, uterine anomaly which prevented placement, cervical cancer, or history of postpartum or postabortal sepsis and those who desired pregnancy in the next year were excluded.

All participants provided written informed consent before enrollment. At enrollment, we collected baseline demographic, medical and reproductive health data via written questionnaire and ensured women had negative testing for *Neisseria gonorrhoeae* and *Chlamydia trachomatis* within the prior 3 months. If results were not available, testing was performed on the day of delivery. At delivery, women with untreated gonorrhea or chlamydia, clinical evidence of infection or prolonged rupture of membranes and those no longer desiring the LNG-IUD were excluded. Women were randomized to either immediate postplacental insertion of the LNG-IUD during cesarean or delayed insertion 4–8 weeks after delivery. Study personnel determined randomization allocation via sequentially numbered, sealed, opaque envelopes. A researcher who was not involved with the conduct of the study prepared the envelopes, using a computer-generated blocked-randomization scheme, in a 1:1 ratio. Randomization was stratified by site.

For women randomized to postplacental IUD placement, women who could not undergo IUD insertion within 10 min of placental delivery (i.e., due to hemorrhage or surgical complication) were excluded. A trained attending physician performed all insertions. The Principal Investigator (A.W.) trained all participating physicians. The EH study site required additional training in transcervical placement, as investigators at that site had little prior experience inserting the LNG-IUD. During cesarean delivery, the LNG-IUD inserter was inserted through the hysterotomy site. The surgical assistant then placed a finger on the IUD to position the IUD at the uterine fundus. The inserter was then removed, and a ring forceps was inserted through the hysterotomy site to grasp the strings and insert them through the cervix from above, into the vagina. The ring forceps was then immediately removed from the sterile field to prevent vaginal contamination of the pelvic cavity, and the site was closed per the routine of the operating physician. In our initial protocol, strings were trimmed flush with the cervix via speculum exam after the surgery. We then changed our practice to trim strings prior to insertion by cutting strings at the point where they "locked" into the notch on the LNG-IUD inserter, leaving the strings approximately 25 cm long, without trimming after the cesarean. At 4–8 weeks, women were assessed for the presence of the IUD by speculum examination; strings were trimmed as necessary during this exam. If strings were not visible, presence of the IUD was assessed by ultrasound.

Women randomized to delayed insertion were scheduled for a visit 4–8 weeks after delivery. At this visit, all women with no evidence of cervical or vaginal infection underwent LNG-IUD insertion in the standard transcervical fashion by a trained attending physician.

We conducted follow-up assessments at 3, 6 and 12 months after delivery. We initially required in-clinic follow-up at all time points but changed the protocol to allow for telephone contact at 3 and 6 months. Research staff members conducting follow-up assessments were blinded to participant allocation. Follow-up data collection included contraceptive method, satisfaction with method and assessment for expulsion. We measured satisfaction with the IUD using a 5-point scale, ranging from 1 ("very unsatisfied") to 5 ("very satisfied"). At the 12-month visit, participants also underwent urine pregnancy testing and pelvic examination. For women who did not have the IUD placed or had the IUD placed off protocol, those who experienced expulsion without subsequent reinsertion and those who had the IUD removed for other reasons, all follow-up was performed via telephone contact only, with no in-person visit at 12 months. We made up to three telephone attempts to reach each participant at all of the follow-up visits and sent a letter if telephone attempts were unsuccessful.

Our primary study outcome was use of the LNG-IUD at 12 months after delivery. Secondary outcomes included insertion per protocol, expulsion, satisfaction with the IUD and complications. To estimate sample size, we made assumptions based on the existing literature, which included only observational studies at the time of study design and initiation. We